



U.S. Department of Justice

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Southern District of New York*

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October 21, 2019

By ECF

The Honorable Kimba M. Wood
United States District Judge
Southern District of New York
Daniel Patrick Moynihan United States Courthouse
500 Pearl Street
New York, NY 10007

Re: United States v. Todd Schlifstein, 18 Cr. 217 (KMW)

Dear Judge Wood:

The Government respectfully submits this letter in connection with the sentencing of defendant Todd Schlifstein (“the defendant” or “Schlifstein”), which is scheduled for 11:00 a.m. on Monday, October 28, 2019. As stipulated in the defendant’s plea agreement and calculated by the Probation Department, the United States Sentencing Guidelines (“U.S.S.G.” or “the Guidelines”) sentencing range applicable to the defendant is 46 to 57 months’ imprisonment. For the reasons set forth below, the Government respectfully submits that a sentence at the high end of the Guidelines range would be sufficient, but not greater than necessary, to serve the legitimate purposes of sentencing.

I. Offense Conduct

As detailed in the Presentence Investigation Report dated September 17, 2019 (“PSR”), Schlifstein, a doctor of osteopathic medicine, accepted bribes and kickbacks from the pharmaceutical company Insys Therapeutics (“Insys”) in exchange for prescribing Insys’s fentanyl-based drug, Subsys. Specifically, Schlifstein collected \$127,100 in purported speaker fees from Insys from March 2014 to September 2015. In return, he prescribed enough Subsys to account for more than \$2 million in net sales for Insys.

A. Subsys and the Insys Speakers Bureau

Fentanyl is a synthetic opioid approximately 50 to 100 times more potent than morphine. It is classified as a Schedule II controlled substance under the Controlled Substances Act, meaning that it has a high potential for abuse. (PSR ¶ 34).

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In January 2012, the U.S. Food and Drug Administration (the “FDA”) approved Subsys, a fentanyl spray administered sublingually (i.e., under the tongue), for the management of breakthrough pain in cancer patients who were already receiving and tolerant to opioid therapy for their underlying persistent cancer pain. The Subsys label expressly warned against prescribing the drug to patients who were not already opioid tolerant, “[d]ue to the risk of fatal respiratory depression.” In March 2012, Subsys entered the commercial market. (PSR ¶ 33).

Unlike some fentanyl-based medications, such as transdermal patches, Subsys is in a category of drugs known as Transmucosal Immediate Release Fentanyl (“TIRF”) products, which are rapid-onset opioids designed to treat breakthrough pain in opioid-tolerant adults with cancer. Because of the risk of misuse, abuse, and addiction associated with TIRF products, including Subsys, practitioners must enroll in a mandated FDA program known as the Transmucosal Immediate Release Fentanyl Risk Evaluation and Mitigation Strategy program (the “TIRF REMS Program”) and complete required training and testing in order to prescribe Subsys and other TIRF products for outpatient use. Patients, too, must enroll in the TIRF REMS Program in order to be prescribed TIRF products, including Subsys. (PSR ¶ 35).

In August 2012, Insys established the Insys Speakers Bureau, a roster of doctors and other health care providers paid purportedly to provide educational presentations, known as speaker programs, about Subsys. Rather than recruit potential speakers based on their qualifications as educators, Insys targeted speakers who would be willing to prescribe Subsys in large volumes. Insys executives instructed sales representatives to focus their time and resources on a few select doctors and provide them with lucrative speaker fees, among other benefits, in exchange for prescribing high quantities of Subsys. After the Speakers Bureau launched, Insys executives tracked and circulated statistics regarding speakers’ prescribing habits. For a time, Insys calculated each speaker’s “ROI”—return on investment—by dividing the sales generated from the practitioner’s Subsys prescriptions by the amount Insys had paid that practitioner in speaker fees. (PSR ¶¶ 22, 50).

B. Schlifstein’s Participation in the Conspiracy

Schlifstein, a doctor of osteopathic medicine, was certified in physical medicine and rehabilitation. Together with codefendant Jeffrey Goldstein, he owned and operated a medical practice on the Upper East Side beginning in 2009. The business included a “medical spa” devoted primarily to cosmetic procedures, such as skin peels and cellulite-removal treatments. (PSR ¶¶ 28, 121).

Goldstein joined the Insys Speakers Bureau around spring 2013. Over the following months, Schlifstein attended a number of Goldstein’s Insys-sponsored speaker programs, which were predominantly non-educational social affairs held at fancy Manhattan restaurants. (PSR ¶ 60). In October 2013, Schlifstein asked his Insys sales representative how he, too, could become an Insys speaker. In late October, an Insys executive flew to New York to meet with Schlifstein over dinner at one of Goldstein’s purported speaker programs. After the dinner—which did not include any educational presentation—the group went to a strip club Schlifstein frequented and rang up \$4,100 in charges for drinks, a private room, and lap dances for Schlifstein and Goldstein. Insys paid the bill. (PSR ¶ 63).

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In the days and weeks that followed, Schlifstein informed Insys that he would prescribe Subsys to a number of new patients, and Insys told Schlifstein it would make him a speaker. Around early November 2013, Schlifstein and his Insys sales representative met in Schlifstein's office, where Schlifstein looked through his calendar of upcoming appointments and identified specific patients to whom he would begin prescribing Subsys. (PSR ¶ 64). On November 18, 2013, Insys nominated Schlifstein to its Speakers Bureau. By early March 2014, he was hosting non-educational speaker programs for \$2,400 per dinner. (PSR ¶ 65).

The link between Schlifstein's prescribing habits and his thirst for speaker fees was blatant. Schlifstein prescribed Subsys to nine patients from March 2012 until his strip-club outing with Insys executives in late October 2013. In the months that followed—a period when Schlifstein was eager to prove his value to Insys because his nomination to the Speakers Bureau was pending—his Subsys prescriptions increased dramatically. He prescribed Subsys to eight new patients in November 2013, and to an additional nine new patients from December 2013 until his first speaker program in early March 2014. Insys was pleased: In early April 2014, it rewarded Schlifstein by raising his speaking fee to \$3,000 per dinner. (PSR ¶ 65).

Insys paid Schlifstein a total of \$74,400 to conduct 26 purported speaking programs from March through September 2014. But the company abruptly decreased Schlifstein's allotment of speaker programs for the rest of the year because his Subsys prescriptions were leveling off. (PSR ¶ 68). In response, Schlifstein lobbied for more programs—including by contacting Insys's Regional Sales Director directly—and drastically ramped up his Subsys prescriptions. (PSR ¶ 69). He prescribed more than 3,756,000 micrograms of Subsys in the fourth quarter of 2014—more than twice what he had prescribed the previous quarter. (PSR ¶ 70). Insys gave him more speaker programs as a result, paying him \$42,000 for 14 dinners from December 17, 2014, through June 2015. Having learned his lesson, Schlifstein continued prescribing Subsys in ever-higher quantities. In the second quarter of 2015, his Subsys prescriptions totaled 7,368,000 micrograms. (PSR ¶ 71). Schlifstein was the 19th-highest Subsys prescriber nationally in that quarter, accounting for total net sales for Insys of approximately \$593,373. (PSR ¶ 73). After June 18, 2015, however, Schlifstein spoke at only two speaker programs and did not prescribe Subsys to any new patients. (PSR ¶ 74).

The vast majority of Schlifstein's speaker programs were not educational. Schlifstein drank alcohol excessively at many of the dinners, and he regarded the events as opportunities to treat his friends and staff to social outings at fancy restaurants, as was apparent from photos from his speaker programs that Schlifstein posted to social media, including the photos attached hereto as Exhibits A and B. (PSR ¶¶ 53, 58). In September 2014, Schlifstein's Insys sales representative learned that a compliance monitor planned to attend an upcoming speaker program. Having attended many of the more than 20 speaker programs Schlifstein had been paid to conduct over the past six months, the representative worried that Schlifstein would not know how to conduct a compliant and educational speaker program, complete with the mandatory slide presentation Insys provided to Schlifstein before each event, in the monitor's presence. Accordingly, the sales representative scrambled to teach Schlifstein what to say and do during the dinner. (PSR ¶ 57).

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Sign-in sheets for Schlifstein's speaker programs were often forged and falsified with names and purported signatures of people who had not, in fact, attended. The forgeries created the illusion that Schlifstein had given educational presentations to an appropriate audience of health care professionals, and that everyone was obeying a \$125 cap on food and drinks per attendee. Schlifstein knew that sign-in sheets for his speaker programs were being forged and falsified, and he sometimes instructed his Insys sales representative to ask employees from his medical practice to sign sheets for speaker programs they had not attended. (PSR ¶ 55).

II. Procedural History and Sentencing Guidelines Calculation

Schlifstein was arrested on March 16, 2018, for offenses alleged in Indictment 18 Cr. 217 (KMW) (the "Indictment"). (PSR ¶ 80). On June 26, 2018, he pled guilty to Count One of the Indictment, charging him with conspiracy to violate the Anti-Kickback Statute, in violation of 18 U.S.C. § 371. (PSR ¶ 12).

Schlifstein pled guilty pursuant to a plea agreement in which the parties stipulated that his offense level is 23 and that his Criminal History Category is I, for a recommended Guidelines range of imprisonment of 46 to 57 months and a recommended fine range of \$20,000 to \$200,000. (PSR ¶ 13). The Guidelines offense level of 23 results from a base offense level of 8, *see* U.S.S.G. § 2B4.1(a); a 16-level increase because the value of the improper benefit Schlifstein conferred on Insys—i.e., the net value to Insys of the Subsys prescriptions Schlifstein wrote in exchange for speaker fees—exceeded \$1,500,000 but did not exceed \$3,500,000,¹ *see* U.S.S.G. §§ 2B4.1(b)(1)(B), 2B1.1(b)(1)(H); a 2-level increase because Schlifstein, a doctor, abused a position of public or private trust in a manner that significantly facilitated the commission of the offense, *see* U.S.S.G. § 3B1.3; and a 3-level reduction for Schlifstein's acceptance of responsibility, *see* U.S.S.G. § 3E1.1(a)-(b).

Schlifstein also signed a Consent Preliminary Order of Forfeiture in which he agreed to forfeit \$127,100, representing the bribe proceeds disguised as speaker fees that Schlifstein collected from Insys.²

In the PSR, the Probation Department concurs with the parties' Guidelines calculations (PSR ¶¶ 87-100, 135) and recommends that the Court sentence Schlifstein principally to 36 months' imprisonment (PSR at 31).

¹ Schlifstein's prescriptions accounted for net sales of Subsys for Insys totaling approximately \$2,777,452. Contrary to the suggestion in Schlifstein's sentencing submission (*see* Def. Mem. 23-24), the Guidelines analysis—which Schlifstein stipulated to in his plea agreement—did not consider the *gross* sales value, which totaled approximately \$3,219,741.

² Schlifstein is also jointly and severally liable for restitution to victims who paid for the Subsys he prescribed, including a restitution obligation to Medicare of approximately \$1,758,189.06. The Government has 90 days following the date of sentence to provide the Court with full information concerning the victims and the amount of restitution owed to each of them. *See* 18 U.S.C. § 3664. Because the Government is still gathering information relevant Schlifstein's restitution obligation, it intends to submit a proposed restitution order after sentencing.

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III. The Court Should Impose a Prison Sentence at the High End of the Guidelines Range

A prison sentence for a term at the high end of the Guidelines range of 46 to 57 months is warranted in this case based on the sentencing factors the Court must consider.

The Guidelines still provide important guidance following *United States v. Booker*, 543 U.S. 220 (2005), and *United States v. Crosby*, 397 F.3d 103 (2d Cir. 2005). The Guidelines provide the “starting point and the initial benchmark” in sentencing proceedings. *Gall v. United States*, 552 U.S. 38, 49 (2007). After that calculation, the Court must consider the factors outlined in 18 U.S.C. § 3553(a), which include, among other things, the nature and circumstances of the offense and the need to deter criminal conduct and promote respect for the law. *Id.* at 49-50 & n.6.³

A. Nature and Circumstances of the Offense and the Need to Reflect the Seriousness of the Offense, Promote Respect for the Law, and Provide Just Punishment

Schlifstein’s violation of the Anti-Kickback Statute is especially egregious because it involved a highly addictive and dangerous narcotic. Subsys is one of the commercially available TIRF medications, a class of drugs far more potent than other opioids, including oxycodone and fentanyl patches. A single dose, if administered to someone who is not sufficiently opioid tolerant, could be lethal. The Guidelines do not account for the risk Schlifstein’s conduct caused to his patients and the public: the Guidelines range would be the same if Schlifstein had taken kickbacks in exchange for prescribing or recommending \$2 million worth of a particular brand of wrist brace, or aspirin.

Allowing bribes to influence any doctor’s prescribing decision would be troubling. When the prescription decision involves a drug as potent as fentanyl, corrupt payments create an enormous hazard and public health risk. Schlifstein accepted bribes in return for directing his patients to take one of the most potent painkillers that is available commercially. The sentence imposed must reflect the seriousness of that conduct.

Schlifstein’s conduct here is particularly egregious because the bribes did not merely cause Schlifstein to favor Subsys over other TIRF drugs he otherwise would have prescribed. Rather, the corrupt payments induced Schlifstein to prescribe Subsys to many patients who otherwise would not have received any potent and dangerous TIRF products whatsoever. In his sentencing submission, Schlifstein downplays the effect the bribes had on his prescribing habits. He asserts,

³ The factors outlined in Section 3553(a) are: (1) “the nature and circumstances of the offense and the history and characteristics of the defendant”; (2) the four legitimate purposes of sentencing, namely, the need (a) “to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense,” (b) “to afford adequate deterrence to criminal conduct,” (c) “to protect the public from further crimes of the defendant,” and (d) “to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner”; (3) “the kinds of sentences available”; (4) the Guidelines range itself; (5) any relevant policy statement by the Sentencing Commission; (6) “the need to avoid unwarranted sentence disparities among defendants”; and (7) “the need to provide restitution to any victims.” 18 U.S.C. § 3553(a)(1)-(7).

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for example, and that the speaker fees he received from Insys did not influence his decisions to prescribe Subsys except during a brief period in the fourth quarter of 2014, and that even then, he merely “began favoring Subsys over other competing treatments,” rather than prescribing Subsys to patients who did not need powerful and dangerous TIRF products. (Def. Mem. 19).

Prescription records prove otherwise. Schlifstein indeed prescribed limited quantities of Subsys before joining the Insys conspiracy in approximately late October 2013. But an analysis of Schlifstein’s prescribing data shows that after he joined the conspiracy, his Subsys prescriptions alone far exceeded the total prescriptions of all TIRF drugs he had written during prior periods when he was not being promised or paid bribes. The chart in Paragraph 75 of the PSR, a copy of which is attached hereto as Exhibit C, is illustrative. It shows, for example, that Schlifstein wrote an average of approximately 32 TIRF prescriptions per quarter in 2011, and far fewer TIRF prescriptions per quarter in 2010 and 2012. In contrast, in the fourth quarter of 2013, when Schlifstein ramped up his Subsys prescriptions in a successful effort to become a speaker, he wrote approximately 41 TIRF prescriptions, approximately 26 of which were for Subsys; in the first quarter of 2014, he wrote approximately 53 TIRF prescriptions, approximately 39 of which were for Subsys; and in the second quarter of 2015, he wrote approximately 81 TIRF prescriptions, including 73 for Subsys. (PSR ¶ 75).

There was no material change in Schlifstein’s patient population that could explain the drastic change in his prescribing habits. Few of his patients, if any, suffered from breakthrough cancer pain, the only condition the FDA approved Subsys to treat. If anything, Schlifstein’s TIRF prescriptions should have been falling from 2013 through 2015, not rising. During that period, Schlifstein increasingly focused on and worked at the “medical spa” portion of his business. The spa catered to customers seeking cosmetic procedures, not to patients with the type of grave conditions that might warrant prescriptions for TIRF drugs.

Schlifstein’s claim that the prospect of Insys speaker fees influenced his prescribing decisions only during a brief period in late 2014 ignores the facts. As noted above, Schlifstein’s Subsys prescriptions increased dramatically in late 2013, shortly before Schlifstein began conducting speaker programs. That Schlifstein was not yet collecting speaking fees in the fourth quarter of 2013 does not mean, as Schlifstein suggests (*see* Def. Mem. 18-19), that he was prescribing Subsys for non-corrupt reasons. To the contrary, Schlifstein prescribed more Subsys because Insys promised to make him a paid speaker in return. Although Schlifstein did not conduct a speaker program until early March 2014, Insys nominated him to its Speakers Bureau months earlier, on November 18, 2013, shortly after Schlifstein’s meeting and strip club outing with Insys executives. Not coincidentally, Schlifstein, who had written approximately six Subsys prescriptions in the third quarter of 2013, prescribed Subsys approximately 26 times in the fourth quarter of 2013. Schlifstein’s corrupt actions thus began before his brother died suddenly in January 2014, undermining Schlifstein’s explanation that grief from that tragedy is what “impaired his ability to resist overtures from Subsys’ representatives that he compromise his independent judgment.” (Def. Mem. 20-21).

Schlifstein’s statements that he “gr[e]w disenchanted with the Subsys speaker series” and stopped prescribing Subsys to new patients after June 18, 2015, because he was “[u]ncomfortable with the constant pressure he was receiving from Subsys’ representatives to prescribe Subsys”

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(Def. Mem. 19) also ring hollow. As an initial matter, if Schlifstein prescribed Subsys to his patients because he thought it was the best treatment for them, then he should not have stopped doing so merely because some Insys employees tried to pressure him. Schlifstein's feelings about the conduct of the company and its employees should not have affected his decisions about which medications to prescribe to his patients. That Schlifstein even advances this argument reflects the extent to which he let impermissible factors influence his prescribing decisions, contrary to his Osteopathic Oath. If Schlifstein felt as disenchanted with the Insys speaker program as he now claims, the proper response would have been to quit the Insys Speakers Bureau. He did not do so: he conducted speakers programs in July and September 2015. While Schlifstein states that he conducted those programs "because he had previously committed to them" (Def. Mem. 19), there is no indication that he donated or refused the \$7,400 in total speaker fees Insys paid him for those two dinners.

Tellingly, Schlifstein posted what is attached hereto as Exhibit B to his social media account following an Insys speaker dinner held June 17, 2015—the same time he stopped prescribing Subsys to new patients. The post shows Schlifstein getting paid \$3,000 to enjoy a free meal and drinks with "great friends" at a fancy restaurant. If Schlifstein felt remotely "disenchanted" or "[u]ncomfortable" about his corrupt arrangement with Insys, he never would have posed for and posted that photo.

In truth, what changed in mid-2015 is that people began scrutinizing the Insys speaker program and the prolific Subsys prescribers who profited from it. An investigative journalist published an exposé,⁴ law enforcement authorities opened investigations, and Insys tightened up its compliance protocols. Moreover, Insys stopped lavishing its Speakers with numerous speaker programs per quarter, significantly curtailing how much it was paying doctors around the country, including Schlifstein. Amid this shift, Schlifstein stopped prescribing Subsys to new patients because his profit incentive to do so no longer outweighed his fear of getting caught.

B. Need to Deter Criminal Conduct

A substantial sentence is also necessary in this case to afford adequate deterrence to criminal conduct. *See* 18 U.S.C. § 3553(a)(2)(B).

According to the CDC, drug overdoses killed more than 70,000 people in the United States in 2017, and more than two-thirds of those deaths involved opioids. *See* <https://www.cdc.gov/media/releases/2018/p1221-complexity-drug-overdose.html> (last visited October 19, 2019). This epidemic starts with prescribing physicians, like this defendant, whose decisions to prescribe highly addictive and potentially deadly medications were motivated by the prospect of financial gain or any other consideration besides a patient's best interests. The medical community follows these cases closely. A prison sentence at the high end of the Guidelines range would help send a strong message that accepting bribes in return for prescriptions will result in a substantial term of incarceration, particularly when the prescriptions are for dangerous and addictive products.

⁴ *See* Roddy Boyd, *The Black World of Insys Therapeutics*, SOUTHERN INVESTIGATIVE REPORTING FOUNDATION, July 14, 2015, *available at* <http://sirf-online.org/2015/07/14/the-darkening-world-of-insys-therapeutics/> (last visited October 19, 2019).

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The challenges in investigating and deterring similar bribery schemes involving medical providers heighten the need for deterrence. The law does not prohibit financial relationships between pharmaceutical companies and physicians outright. Physicians are permitted, for example, to accept fees from pharmaceutical companies to conduct educational speaker programs. Conducted properly, those programs enable physicians to use their expertise and experience to teach other doctors about potentially beneficial treatments. Against this backdrop, it is difficult for law enforcement to detect whether a payment to a physician is legitimate or corrupt. *See United States v. Heffernan*, 43 F.3d 1144, 1149 (7th Cir. 1994) (Posner, J.) (“Considerations of (general) deterrence argue for punishing more heavily those offenses that either are lucrative or are difficult to detect and punish, since both attributes go to increase the expedited benefits of a crime and hence the punishment required to deter it.”); *see also United States v. Zukerman*, 897 F.3d 423, 429 (2d Cir. 2018) (citing *Heffernan*).

When doctors let personal financial interests influence treatment decisions, patients pay the price in increased medical costs and increased health risks. A substantial sentence would help deter health care providers from crossing the line between collaboration and corruption.

C. History and Characteristics of the Defendant

In his sentencing submission, Schlifstein appropriately highlights positive aspects of his personal history and characteristics, including the obstacles he overcame to put himself through medical school and his devotion to his late brother’s family, that warrant consideration at sentencing. (*See* Def. Mem. 5-17, 20-21). But Schlifstein mischaracterizes his record as a physician and the collateral consequences that will flow from his conviction in this case.

This conviction is not the only stain on Schlifstein’s professional record. New York’s Bureau of Professional Misconduct (“BPMC”) has investigated Schlifstein’s prescribing habits multiple times over the years, including a 2012 inquiry based on a referral from CVS/Caremark and a 2013 case based on a complaint from the relative of a Schlifstein patient who died from prescription drug abuse. Public records, including those attached hereto as Exhibit D, show that BPMC ultimately filed a complaint alleging that Schlifstein, from 2009 to 2014, “failed to render appropriate care and treatment” to eight patients, including by “inappropriately” prescribing those patients controlled substances. (Ex. D at 11). In 2017—*before* his arrest in this case—Schlifstein admitted that he “cannot successfully defend against at least one of the acts of misconduct alleged,” and he agreed, among other things, to forfeit his license to prescribe “controlled substances and all non-controlled mood-altering and/or abusable medications.” (*Id.* at 4). Accordingly, Schlifstein’s criminal conduct in this case was not an aberration so much as a continuation or escalation of a pattern of professional misconduct. And although Schlifstein states that he “lost his medical license, his medical practice, and his ability to do the job that he loves” as a result of his “grave mistake” in the instant case (Def. Mem. 3), his ability to practice medicine has been severely restricted since before his arrest due to actions that predated his participation in the Insys conspiracy.

Finally, it bears emphasis that Schlifstein acted purely out of greed, not desperation. Even without Insys’s help, his business was thriving, thanks in large part to his increased focus on his

